DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 16, 2014

W & H DENTALWERK BÜRMOOS GMBH
Mag. Anja Lindner
Manage Regulatory Affairs
Ignaz-Glaser-Strasse 53
A - 5111 Bürmoos
AUSTRIA

Re: K133488
Trade/Device Name: Piezomed SA 320
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone cutting instrument and accessories
Regulatory Class: II
Product Code: DZI
Dated: September 09, 2014
Received: September 09, 2014

Dear Ms. Lindner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number:

K133488

Device Name:

Piezomed SA-320

Indication for Use:

Piezomed is a piezoelectric ultrasonic device, consisting of handpieces and associated instruments, intended for:

- Bone Cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic, and surgical endodontic procedures;
- Scaling applications, including:
    - Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits;
    - Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
    - Endodontic: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha-condensation and retrograde preparation;
    - Restorative and Prosthetics: Cavity preparation, removal of prostheses, finishing of crown preparations.

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Applicant and Owner	W & H DENTALWERK BÜRMOOS GMBH Ignaz-Glaser-Strasse 53 A - 5111 Bürmoos Austria Tel.: 0043 -6274 / 6236 -397 Fax: 0043 -6274 / 6236 -55
Registration Number	9681479
Contact Person	Mag. Anja LINDNER
Date of Submission	November 7th, 2013
Device Name	Piezomed SA-320
Classification Name	Drill, Bone, Powered
Regulation Number	21 CFR 872.4120
Product Code	DZI
Predicate Devices	“Piezosurgery Touch”, Mectron S.P.A. / Italy, K122322

Device Description	Piezomed SA-320 is an ultrasonic drive unit intended for the treatment of organic hard and soft tissue in dental surgery, implantology, maxillofacial surgery and periodontics. The device consists of the control unit, the foot control, the piezo handpiece incl. cable, an irrigation tubing set, the instrument set “Bone” and the corresponding instrument changer, and various accessories such as the stand and a motor rest. The unit provides an instrument (tip) detection, choosing automatically the power class fixed for the attached instrument (tip). Within certain limits the user can change the pre-adjusted power settings manually. Furthermore, the user can choose between three adjustable working modes (Power, Basic, Smooth). A boost function enables a short-term power increase by 20 %. A LED lighting ring provides illumination of the surgical site.

Intended Use:

Piezomed is a piezoelectric ultrasonic device, consisting of handpieces and associated instruments, intended for:

- Bone Cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic, and surgical endodontic procedures;
- Scaling applications, including:
  - Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits;
  - Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
  - Endodontic: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha-condensation and retrograde preparation;
  - Restorative and Prosthetics: Cavity preparation, removal of prostheses, finishing of crown preparations.

Technological Characteristics

W&H´s Piezomed SA-320 represents a revised and improved version of the predicate device.
The technical principle is the same as within the predicate device (piezo-electric principle).
The main technological characteristics are the same or, at least, quite similar to those of the comparable product.

Technological Characteristic	Subject device	Predicate Device (K122322)
User Interface	Consisting of: control unit, foot control, handpiece, instruments/tips	Consisting of: control unit, foot control, handpiece, inserts
Mains supply	100 – 240 V / 50-60Hz	100-240 V / 50-60 Hz
Max. power consumption	90 VA	120 VA
Operating frequency	Automatic scan, from 24 KHz to 32 KHz	Automatic scan, from 24 KHz to 36 KHz
Energy source	Piezo-ceramic oscillating system	Piezo-ceramic oscillating system
Coolant flow rate	at least 50 ml	max. 75 ml
LED system	4 LEDs	1 LED
Activation of device	Mains switch on control unit	Mains switch on control unit
Cleaning/Sterilization	Thermo washer disinfection approved, Steam sterilization at 132°C (270°F)	Thermo washer disinfection approved, Steam sterilization at 132°C (270°F)

	Autoclaveability	**Handpiece:** Dynamic air removal sterilizer, 132°C (270°F) for 4 minutes, Drying time: 20 - 30 min **Blank, polished instruments/tips:** Dynamic air removal sterilizer, 132°C (270°F) for 4 minutes, Drying time: 20 - 30 min **Diamond coated instruments/tips:** Single-use only	**Handpiece:** Dynamic air removal sterilizer, 132°C (270°F) for 4 minutes Drying time: 20 min **Blank, polished inserts / tips:** Dynamic air removal sterilizer, 132°C (270°F) for 4 minutes, Drying time: 20 min **Diamond coated inserts / tips:** Single-use only
	Range of instruments / tips	24 variants for various applications	31 variants for various applications
	Materials of the instruments / tips	Stainless steel – polished or diamond-coated	Stainless steel – polished or diamond-coated
Comparison of the device to the predicate device	The target field of application, the intended use, functions and technological features, performance parameter and material are the same or, at least, quite similar to those of the predicate device. The product comparison did not raise new or different questions regarding safety and efficacy. The new device is substantially equivalent to the predicate device.		
Performance Testing	Electrical Safety Tests according to IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. Electromagnetic Compatibility Test according to IEC 60601-1-2:2007: General requirement for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests Type testing according to ISO 22374:2005: Dentistry -- Dental handpieces -- Electrical-powered scalers and scaler tips Software validation according to IEC 62304:2006: Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software		

	Mechanical strength test according ANSI/AAMI ES 60601-1:2005 Usability validation according to IEC 62366:2007 Thermal safety according to the standard IEC 62471:2006: Photobiological safety of lamps and lamp systems Flow rate testing, evaluation of biocompatibility and sterilizability, various functionality and lifecycle tests as well as further bench tests demonstrate substantial equivalence.
Clinical Testing	Clinical data were not needed for this new product.